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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,213	02/12/2004	Graham P. Belfield	3764-152	2071

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EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/776,213	BELFIELD ET AL.
	Examiner	Art Unit
	Gerald G. Leffers Jr., PhD	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _17 December 2004_.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-29_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-9,11-18,20 and 22-29_ is/are rejected.

7)☒ Claim(s) _10,19 and 21_ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _12 February 2004_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☒ All   b)☐ Some *   c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☒ Certified copies of the priority documents have been received in Application No. _09/743,194_.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _2/12/2004_.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☒ Other: _Exhibit A; Search Result Seq Id No: 2_

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II (claims 1-29 directed to SEQ ID NO: 2) in the reply

filed on 12/17//2004 is acknowledged. Because applicant did not distinctly and specifically point

out the supposed errors in the restriction requirement, the election has been treated as an election

without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

Receipt is acknowledged of an information disclosure statement (IDS) filed on

2/12/2004. The signed and initialed PTO Form 1449 has been mailed with this action. The four

search results (e.g. "B-Door External...") have not been considered as they were not present in

the patent file. It is further noted that in any case there is no indication of the publication date for

these references or where the information is available to the public (i.e. the publisher). If

applicants want the information therein to be considered, the information should be resubmitted

in a form consistent with 37 CFR 1.98.

Specification

The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to which the claims are directed.

The following title is suggested: Compositions and Methods Using the Yeast HOR7

Promoter.

The disclosure is objected to because of the following informalities: at several places in the specification there are odd placements of letters and symbols at the beginning and ending of words. For example, on page 2 at lines 5 & 6, the term "Ayeast promoter@" is used. It appears as though the characters "A" and "@" are meant to be quotation marks around the word "yeast". Another example occurs at page 25, line 14. Numerous instances of these typographical errors are present throughout the specification. It would be remedial to amend the specification in each instance to clearly indicate that what is intended.

Claim Objections

Claims 10 & 21 are objected to because of the following informalities: each recites nonelected inventions (i.e. the different vector constructs comprising the nonelected promoter elements). It would be remedial to amend the claims to be directed to the two elected embodiments (i.e. pYMR251AP + luc and pYMR251AP). Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claims read on nonstatutory subject matter. The claims are directed to "A yeast promoter which comprises at least [17, 50, 100, 200, 300 or 400] contiguous nucleotides of an isolated and purified polynucleotide which is SEQ ID NO: 2..." without any explicit limitation as to what context the promoter is found. The terms "isolated and purified polynucleotide" refer to SEQ ID NO:2 and not to the promoter that

is claimed. As written, the claim can be interpreted to encompass any promoter that meets the

limitation of comprising at least 17 contiguous nucleotides of SEQ ID NO: 2, regardless of the

context in which the promoter is found. By this interpretation, the rejected claims read on the

native YMR251WA promoter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunt et al (see

the attached search report for Accession No. Z48639) as evidenced by Goffeau et al (Science,

1996, Vol. 274, pages 546-567; see the entire reference).

Accession No. 48639 corresponds to *S. cerevisiae* cosmid clone 9920, which has 99.6

identity with SEQ ID NO: 2 over its entire length. The sequence of clone 9920 was submitted by

Hunt et al as early as 10 March 1995 and was apparently available to the public as of 11 August

1997. Goffeau et al teach that the entire *S. cerevisiae* genomic sequence was known by October

1996.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-9, 11-18, 20, 22-28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a yeast promoter, vectors and host cells comprising the promoter. Some of the rejected claims are directed to methods of expressing a protein featuring the promoter, where the promoter comprises at least 17 contiguous nucleotides of SEQ ID NO: 2 and wherein the promoter can drive expression of a nucleic acid molecule encoding the polypeptide when operatively linked thereto. The promoter can be operative in any cell type (e.g. claims 1-6) or must at least be operative in yeast (e.g. claim 8). The promoter may have at least 50, 100, 200, 300, 400 contiguous nucleotides of SEQ ID NO: 2. Alternatively, the promoter can comprise the entire 723 nucleotides of SEQ ID NO:2. For many of the claims, the level of promoter activity is controlled by the level of fermentable carbon source (e.g. glucose) and/or non-fermentable carbon source (e.g. ethanol) in the culture medium.

SEQ ID NO: 2 describes a 723 nucleotide sequence. Even for embodiments featuring a promoter comprising as much as 400 contiguous nucleotides of SEQ ID NO: 2, there are a very large number of possible fragments of SEQ ID NO: 2 that may or may not retain promoter activity. As the number of contiguous nucleotides of SEQ ID NO: 2 that must be present in the claimed promoter or promoter fragment decreases, the number of possible fragments that must

function as a promoter greatly increases (e.g. 17 contiguous nucleotides out of 723). Thus, the

claims are broad genus claims encompassing a large number of fragments of SEQ ID NO: 2 that

must retain functional activity as a promoter element. The size of the genus is further

compounded by the functional limitation in at least some of the claims that the promoter must be

responsive to fermentable and non-fermentable carbon sources in culture media.

SEQ ID NO: 2 is 723 nucleotides in length and describes a sequence that is found at the

beginning of the 7MR251WA (HOR7) reading frame (e.g. see Figure 14 of the instant

specification). The specification describes the cloning of SEQ ID NO: 2 into an expression

vector with an operatively linked reporter polypeptide (i.e. encoding luciferase) to demonstrate

that the sequence described by SEQ ID NO: 2 has promoter activity and that the activity is

responsive to both glucose and ethanol in culture media (e.g. Table 7). No description is

provided, however, for any fragment of SEQ ID NO: 2 of any length that retains promoter

activity. No description is provided in the instant specification for any sequence within SEQ ID

NO: 2 that resembles any known transcription factor binding sequence (e.g. GAL4, etc.). The

specification provides no guidance with regard to which fragments within SEQ ID NO: 2 might

be essential for response to fermentable or non-fermentable carbon sources in culture media.

The prior art does not offset the deficiencies of the instant specification with regard to

description of the claimed invention. Promoter sequences comprising SEQ ID NO: 2 do not

appear to have been described in the prior art. While one of skill in the art might be able to

identify sequences within SEQ ID NO: 2 that possess some homology to binding sites for known

transcription factors, there may bell be other unknown transcription factors required for even the

basal level of promoter activity associated with SEQ ID NO: 2, much less glucose- or ethanol-

responsive activities. Again, there is no description in the art of record for regulatory sequences

that control expression of HOR7 in yeast.

Given the great number of possible fragments of SEQ ID NO: 2 encompassed by the

rejected claims and the limitation that the fragments must retain at least some functional activity,

and given the lack of a structural/functional basis in the instant specification or prior art for the

skilled artisan to envision those embodiments that actually do retain promoter activity, the skilled

artisan would not have been able to envision a sufficient number of the claimed embodiments to

describe the broadly claimed genus. Therefore, the skilled artisan would have reasonably

concluded applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the
> subject matter that the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing

to particularly point out and distinctly claim the subject matter which applicant regards as the

invention.

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "which is SEQ

ID NO: 2" are unclear. As written, the phrase can be applied to the "yeast promoter" itself, or

alternatively, to the isolated and purified polynucleotide. It is thus unclear whether the claim is

limited to SEQ ID NO: 2 or can encompass a promoter comprising sequences in addition to SEQ

ID NO: 2.

Conclusion

Claims 1-9, 11-18, 20 & 22-28 are rejected. Claims 10, 19 & 21 are objected to as being directed to nonelected embodiments. Claim 29 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GERRY LEFFERS
PRIMARY EXAMINER

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

ggl

101/776,213
Exhibit A
Applicant Copy

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Db
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RESULT 6
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DEFINITION Sequence 317 from Patent WO02064766.
ACCESSION   AX536716
VERSION   AX536716.1   GI:25263152
KEYWORDS   .
SOURCE   Saccharomyces cerevisiae (baker's yeast)
ORGANISM   Saccharomyces cerevisiae
            Eukaryota; Fungi; Ascomycota; Saccharomycotina; Saccharomycetes;
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REFERENCE   1
AUTHORS   Contreras,R.H., Eberhardt,I., Luyten,W.H. and Reekmans,R.J.
TITLE   Bax-responsive genes for drug target identification in yeast and
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JOURNAL   Patent: WO 02064766-A 317 22-AUG-2002;
            JANSSEN PHARMACEUTICA N.V. (BE)
FEATURES   Location/Qualifiers
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Query Match   68.8%; Score 497.4; DB 6; Length 680;
Best Local Similarity 99.8%; Pred. No. 6.7e-139;
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Db 9580 AA 9581
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Query Match        99.6%;  Score 720.4;  DB 8;  Length 23498;
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Qy   121  GGGGGCTAAGAAGTCATTCACTTCTTTCTTTTCCTTCGCGGTCCGGACCCGGACCCCTCCT  180
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Qy   181  CTCCCCGCACGATTTCTTCCTTTCATATCTTCCTTTTATTCCGTTGAAGCAACC  240
Db  9040  CTCCCCGCACGATTTCTTCCTTTCATATCTTCCTTTTATTCCGTTGAAGCAACC  9099
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Qy   301  GGTAACGGCACCGTGGCTCGGAAAACGGTTCCTTCGTTCCTTCGTTGCTACAGAGGCTACA  360
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Query Match
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Matches   499; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

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Qy   344  CTAGAACAGGGCTACAGTCTCGATAATAGAATAAGCGCAGTTTATCGGCGGAGG  403
Db   121  CTAGAACAGGGCTACAGTCTCGATAATAGAATAAGCGCAGTTTATCGGCGGAGG  180
Qy   404  GCGGGCGCCCGTTCCCAATAGGGAGGCGCAGTTTATCGGCGGAGGCTCTACTTCTTCCTAT  463
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Qy   464  TTGGGTAAGCCCCTTTCTGTTTTCGGCGTTGCTGCAGGCGTGCTGCAGGCGTGCTGCGCGGGAGAACATA  523
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